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Enhanced Cognitive Rehabilitation to Treat Comorbid TBI and PTSD

**PRINCIPAL INVESTIGATOR:**

Amy Jak, Ph.D.

**CONTRACTING ORGANIZATION:**

Veterans Medical Research Foundation  
San Diego, CA 92161

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14. ABSTRACT This study is a randomized trial of a hybrid treatment for Iraq and Afghanistan Veterans with a history of mild to moderate TBI (mTBI) and PTSD. Emotional symptoms are likely a main cause of the persistence of post-concussive symptoms while thinking problems and emotional control problems associated with mTBI can impede recovery from PTSD. However, there is no PTSD treatment specifically designed to accommodate the difficulties with attention, memory, and problem solving that patients with TBI may have. Therefore, this study integrates therapeutic approaches and tests a modification of cognitive processing therapy (CPT), an empirically supported treatment for PTSD, in which CPT is enhanced with compensatory cognitive rehabilitation principles. The enhanced CPT, called SMART-CPT is being compared to standard CPT in a group of Iraq and Afghanistan Veterans with a history of both mTBI and PTSD. Half of the participants are randomly assigned to receive standard CPT and half to receive SMART-CPT. This year was dedicated recruitment, enrollment, and treatment, with 43 Veterans enrolled and 12 who have completed all treatment sessions, to date.					
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## **INTRODUCTION:**

This study focuses on helping Iraq and Afghanistan Veterans who have a history of mild to moderate traumatic brain injury (TBI) and posttraumatic stress disorder (PTSD) benefit fully from interventions for both conditions. PTSD and TBI occur together frequently in Iraq and Afghanistan Veterans, a combination of conditions which often complicates recovery from either condition. Emotional symptoms are likely a main cause of the persistence of post-concussive symptoms while thinking problems and emotional control problems associated with mild to moderate TBI can impede recovery from PTSD. Prior research has shown that cognitive rehabilitation programs that focus on teaching about what is typical after a head injury, providing people with expectation of positive recovery, and teaching strategies that allow individuals to compensate for their cognitive deficits are effective for treating the thinking symptoms resulting from mild to moderate TBI. These practice standards have been organized into a manualized treatment, Cognitive Symptom Management and Rehabilitation Therapy (CogSMART), which teaches veterans ways to compensate for cognitive difficulties. Psychotherapies that focus on changing thoughts and behaviors related to a traumatic event, such as Cognitive Processing Therapy (CPT), are effective treatments for PTSD and are the standard of care for treatment of the disorder. However, there is no PTSD treatment specifically designed to accommodate the difficulties with attention, memory, and problem solving that patients with TBI may have. Therefore, this study integrates therapeutic approaches and tests a modification of CPT in which CPT is enhanced with compensatory cognitive rehabilitation principles detailed in CogSMART. The enhanced CPT, called SMART-CPT will be compared to standard CPT in a group of Iraq and Afghanistan Veterans with a history of both mild to moderate TBI and PTSD. Half of the participants will be randomly assigned to receive standard CPT and half to receive SMART-CPT.

## **BODY:**

September 15, 2012 to September 14, 2013 was the second fiscal year of the Enhanced Cognitive Rehabilitation to Treat Comorbid TBI and PTSD study. The focus in the second fiscal year was on recruitment, enrollment, assessment, and treatment.

The following are accomplishments as outlined in the Statement of Work:

**Task 1. Study Start Up, Months 1-12:** Complete, see prior annual report.

**Task 2. Recruitment, Enrollment and Treatment and Assessment, months 13-40:**

***2a. Ongoing recruitment of participants:***

In the second fiscal year of this study, the study coordinator has attended meetings in VA-based TBI and PTSD treatment clinics and has been in frequent contact with other study coordinators to facilitate study recruitment. We have also contacted our local Vet Centers as additional recruitment avenues and disseminated study brochures more widely to other relevant clinics within the VA (e.g., Member Services, Polytrauma, Social Work). The study coordinator

has also responded to a steady flow of referrals from clinical providers within the PTSD clinics in the La Jolla, Mission Valley and Oceanside VA locations.

The tables below depict recruitment efforts for the second fiscal year as well as recruitment to date. ‘Pending referrals’ are typically referred individuals with whom we have ongoing efforts to contact or who have expressed interest in enrolling but need to wait for medication stabilization or other scheduling issues.

**Recruitment in second fiscal year:**

<b>Total Referrals</b>	<b>Enrolled</b>	<b>Pending</b>	<b>Declined/ Do not qualify</b>
95	35	6	54

**Recruitment to Date:**

<b>Total Referrals</b>	<b>Enrolled</b>	<b>Pending</b>	<b>Declined/ Do not qualify</b>
109	43	6	60

**2b. Treatment:**

Of the 35 participants enrolled in the second fiscal year. Thirty-two participants have started treatment. To date, 22 participants have been randomized to the SMART-CPT condition and 21 to the standard CPT treatment group. To date, seven participants have completed the study, including all treatments and assessment sessions. Twelve participants have completed the 12 therapy sessions. Fidelity checks of therapy sessions are proceeding on schedule and Dr. Boyd, the study psychologist, continues to meet weekly with Dr. Rodgers for supervision regarding the study treatments. We have had one serious adverse event to date (suicide attempt) which was promptly reported to the VA IRB and the HRPO. The event was also reviewed by the study’s independent medical monitor. All entities concurred that this SAE was not a result of study participation.

**2c. Assessment:**

In the second fiscal year we have completed 34 pre-treatment assessments, ten post-treatment assessments, and six follow-up assessments. To date, 42 enrolled participants have undergone the pre-treatment assessment consisting of neuropsychological, mood, and symptom ratings. Eleven participants have undergone the post-treatment assessment, and seven have completed the follow-up assessment and fully completed the study. All assessments continue to be double-scored and double-entered into the database to insure accuracy in administration, scoring, and data entry and that any errors are not perpetuated.

Preliminary data analysis to determine initial response to and tolerability of treatment reveals that of the 11 individuals completing the post-treatment assessment, the seven Veterans in the standard CPT group had starting PCL scores of 59.59 and ending PCL scores of 35.42 (average change of 24.17 points). The four Veterans in the SMART-CPT group had starting PCL scores of 57.29 and ending PCL scores of 28.75 (average change of 28.54). This data establishes that the treatment results in clinically significant change in PTSD symptoms and that adding cognitive rehabilitation principles to standard CPT does not ‘dilute’ the treatment for

PTSD in any way. In fact, consistent with our primary hypothesis, those receiving SMART-CPT had greater reductions in PTSD symptom severity (as measured by the PCL) than those receiving standard CPT, though this difference is not statistically significant with such a small sample size and only represents preliminary data. Also of note in preliminary analyses is that the non-completion rate is higher in the CPT group (50%) as compared to the SMART-CPT group (24%), a difference that approaches significance ( $\chi^2=2.89$ ,  $p=.09$ ). Furthermore, of those who do not complete the treatment, the SMART-CPT group completes significantly more sessions before dropping out than those from the CPT group (6.6 sessions vs. 2.67 sessions;  $t=-2.53$ ,  $p=.026$ ). Because one concern regarding using CPT in populations with cognitive complaints is early drop-out, these preliminary results are encouraging and suggest that the hybrid SMART-CPT approach is able to significantly enhance treatment retention and session completion in comorbid PTSD and TBI.

### **KEY RESEARCH ACCOMPLISHMENTS:**

- All regulatory approvals were renewed and are current and up to date.
- 43 Veterans have been enrolled in the trial to date
- 7 Veterans have completed all components of the study

### **REPORTABLE OUTCOMES:**

- We presented background data regarding the clinical cognitive presentation of Veterans with comorbid TBI and PTSD at the International Neuropsychological Society Meeting in February 2013; while this data was not drawn from the current participants, it directly informs our work on this study.
- In May 2013, Dr. Jak presented an invited talk at the VA VISN 22 Mental Health and PolyTrauma Conference “Bridging the Gap,” in Long Beach, CA. Her presentation was entitled “Neuropsychological Assessment and Cognitive Profiles in TBI” and included discussion of the treatment concept of SMART-CPT. One of Dr. Jak’s clinical trainees also presented the SMART-CPT concept to the VASDHS PTSD clinics which was received very favorably.
- Dr. Jak was invited and presented the study’s progress and preliminary findings at the Military Operational Medicine Research Program (MOMRP) Research Business Programmatic Concussion/mTBI In-Progress Review (IPR) on 23 and 24 July 2013 at Fort Detrick, Maryland. We performed initial data inspection and conducted preliminary data analysis in preparation for this meeting.
- Dr. Jak was an invited speaker at the 18<sup>th</sup> International Conference & Summit on Violence, Abuse & Trauma, September 8-11, 2013 in San Diego, CA. She was a part of an invited panel entitled “Innovations in TBI and PTSD Research” in which she presented the treatment concept of SMART-CPT.
- Based on work supported by this award, Drs. Lang and Schiehser are submitting an NIH R34 application for additional funding entitled “Integrative Therapy for Post-Traumatic Headache in Veterans of OEF/OIF/OND: Acceptability and Markers of Response.” Dr. Jak is proposed to be a co-investigator on this application, contributing her expertise on

the hybrid treatment concept being studied in “Enhanced Cognitive Rehabilitation to Treat Comorbid TBI and PTSD.”

## **CONCLUSION:**

In summary, “Enhanced Cognitive Rehabilitation to Treat Comorbid TBI and PTSD”, is proceeding very much on schedule and all tasks detailed in the statement of work, including maintaining regulatory approvals, recruitment efforts, assessments, and treatment are proceeding as planned. 43 Veterans have enrolled in the study to date, 35 of them in this reporting period. In the second year and to date, we have encountered only one serious adverse event which was not determined to be a result of study participation. Preliminary examination of the data revealed clinically significant reductions in PTSD symptoms in both treatment groups, but consistent with our primary hypothesis, those receiving SMART-CPT had slightly greater reductions in PTSD symptom severity (as measured by the PCL) than those receiving standard CPT. The SMART-CPT group also had a lower drop-out rate than the standard CPT group and of those who did drop out, the SMART-CPT group completed significantly more sessions before dropping out than those from the CPT group (6.6 sessions vs. 2.7 sessions). These preliminary results would suggest that SMART-CPT enhances treatment adherence and outcomes in a group of Veterans with comorbid PTSD and TBI. Work supported by this award has also led to three presentations and one application for additional funding. At this time, there are not any known barriers to continuing to move forward on schedule and according to the SOW and are optimistic that our successful recruitment efforts can be maintained for the duration of the study.

**REFERENCES:**

None at this time.



**APPENDICES:**

None at this time.

# Enhanced Cognitive Rehabilitation to Treat Comorbid TBI and PTSD

Jak W81XWH-11-1-0641



**DMRDP**

**PI:** Amy Jak, Ph.D.

**Org:** Veterans Medical Research Foundation

**Award Amount:** \$2,075,453

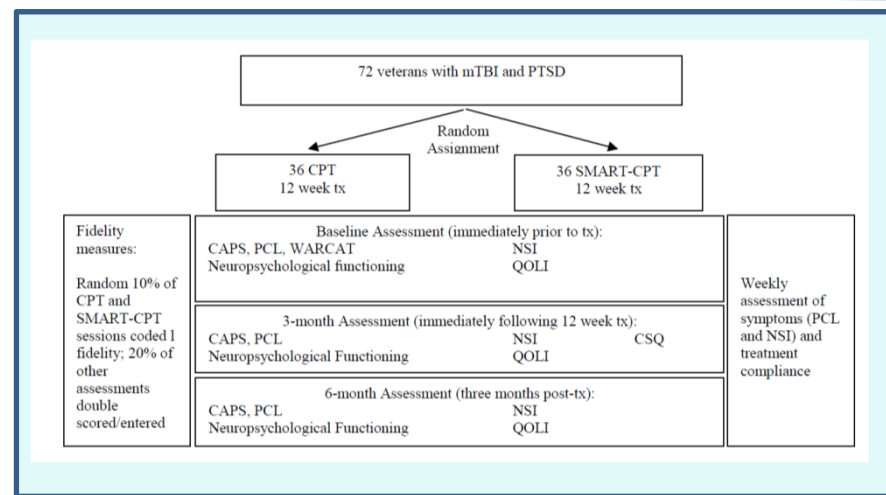
## Study Aim(s)

**Primary Aim 1:** To investigate the efficacy of SMART-CPT in reducing emotional and neurobehavioral symptom severity in veterans with comorbid TBI and PTSD.

**Primary Aim 2:** To investigate the extent of cognitive changes in veterans with comorbid PTSD and TBI following treatment with SMART-CPT.

## Approach

Randomized controlled treatment study to test a modification of Cognitive Processing Therapy (CPT) for PTSD in which CPT is interweaved with compensatory cognitive rehabilitation principles (CogSMART) to create a hybrid treatment, SMART-CPT. The study will examine 72 veterans diagnosed with both PTSD and a history of mild to moderate TBI and randomize half to receive standard CPT and half to receive SMART-CPT for 12 weekly sessions. Veterans will also receive comprehensive symptom, mental health, and neuropsychological assessments at 3 timepoints during the study. The investigation seeks to improve treatment outcomes for combat-related psychological health and develop an evidence-based intervention for treatment of comorbid TBI and PTSD.



Accomplishments: 43 enrolled, 12 in active treatment, 7 completed all study procedures. Prelim. data: clinically significant and slightly higher drop in PCL scores and significantly better treatment adherence in the SMART-CPT group.

## Timeline and Cost

Activities	FY	12	13	14	15
Study Start Up					
Recruitment, Enrollment, Assessment, Treatment					
Ongoing recruitment, treatment, data entry					
Data Analysis, Dissemination of Results					
<b>Estimated Budget (\$K)</b>		<b>\$491</b>	<b>\$514</b>	<b>\$530</b>	<b>\$540</b>

Updated: (October 9, 2013)

## Goals/Milestones

**FY12 Goal** – Study Start Up

- ☒ Regulatory approvals obtained
- ☒ Study staff hired/trained

**FY13 Goals** – Recruitment, Enrollment, Treatment, and Assessment

- ☒ Ongoing recruitment
- ☒ Assessment/Treatment protocol

**FY14 Goal** – Ongoing recruitment, treatment protocol, data entry

- ☐ Ongoing recruitment/enrollment/treatment protocol
- ☐ Data entry

**FY15 Goals** – Data Analysis, Presentation, Publication

- ☐ Data Analysis
- ☐ Dissemination of Results

## Comments/Challenges/Issues/Concerns

Study proceeding as planned; salaries/benefits actual expenditure was approximately under budget since hiring was not complete until midway through FY12 and Co-I funding changes in FY13.

## Budget Expenditure to date

Projected Expenditure: \$1,005,000 Actual Expenditure: \$600,867